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May 15, 1991

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BY FEDERAL EXPRESS

Mr. Bernard J. Schorle
Remedial Project Manager
U.S. EPA Region 5
Office of Superfund (5HS-11)
230 South Dearborn Street
Chicago, Illinois 60604

Dear Mr. Schorle:

Enclosed are the Comments of the Pagel's Pit Landfill Participating PRPs in response to EPA's Proposed Plan for the Winnebago Reclamation Landfill Superfund site.

We urge EPA to consider favorably each of the points made in these Comments in arriving at its Record of Decision in this matter.

Sincerely,

Ridgway M. Hall, Jr.
Susan R. Koehn

Enclosure

cc (w/encl.): Mary Ann LaFaire
Gary Marzorati
John Holmstrom, III
Pagel's Pit Landfill
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COMMENTS BY PAGEL'S PIT LANDFILL PARTICIPATING PRPS IN RESPONSE TO EPA'S PROPOSED PLAN FOR THE WINNEBAGO RECLAMATION LANDFILL SUPERFUND SITE

Submitted to

U.S. Environmental Protection Agency
Region V
Chicago, Illinois

by

The Pagel's Pit Landfill Participating PRPs

May 15, 1991

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IN RESPONSE TO EPA'S PROPOSED PLAN FOR THE
WINNEBAGO RECLAMATION LANDFILL SUPERFUND SITE

INTRODUCTION

The Winnebago Reclamation Landfill ("WRL") site, also known as the Pagel's Pit Landfill, is currently on the National Priorities List established under the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA" or "Superfund"), 42 U.S.C. § 9601 et seq., 40 C.F.R. Part 300. On April 12, 1991, the U.S. Environmental Protection Agency ("EPA") released its "Proposed Plan" setting forth for public comment its recommended remedial action alternatives for the WRL site. "Remedial action" under Superfund is that action necessary "to prevent or minimize the release of hazardous substances so that they do not migrate to cause substantial danger to present or future public health or welfare or the environment". 42 U.S.C. § 9601(24).

These Comments are submitted on behalf of the Pagel's Pit Landfill Participating Potentially Responsible Parties ("PRPs")[1] in response to EPA's Proposed Plan for the WRL site. They begin with a summary of the relevant background information. Next, they respond to the remedial action alternatives recommended by both EPA and the Illinois Environmental Protection Agency ("IEPA") as well as to some of the studies and analyses upon which these

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[1] These are the PRPs who have funded the performance of the Remedial Investigation and Feasibility Study for this site pursuant to an Administrative Order by Consent with EPA Region V.

recommendations are based. We urge EPA to consider favorably each of the points made in these Comments in arriving at its Record of Decision in this matter.

EXECUTIVE SUMMARY

The Winnebago Reclamation Landfill ("WRL") has been operating as a properly licensed solid waste disposal site since 1972. The landfill occupies approximately 40 acres of a 245 acre site located in Winnebago County, which is approximately five miles south of Rockford, Illinois. The site is situated immediately west and downgradient of the former Acme Solvents site, now a heavily contaminated and leaking Superfund site, that operated as an industrial waste disposal site without a permit from 1960 to 1973.

In June 1986, the WRL site was placed on EPA's National Priorities List ("NPL") based on the theory that the landfill was leaking. There is still no direct evidence of any significant amounts of CERCLA hazardous substances emanating from the WRL and extensive data from comprehensive investigations over the past six years show that the site poses no current risk to human health and the environment. EPA has concluded, however, that there are potential risks at the site from possible future residential exposure to contaminated groundwater through ingestion and dermal contact or inhalation while bathing.

To mitigate these supposed risks, EPA's Proposed Plan recommends remedial action Alternatives 5 or 6, which call for, among other things, air stripping or carbon adsorption of

groundwater, respectively. But for the method of groundwater treatment, these alternatives are identical. Both provide for: (1) capping the landfill in accordance with recently revised IEPA regulations; (2) upgrading the landfill's existing gas collection and leachate extraction systems; (3) extracting and transporting the leachate to the POTW for treatment; (4) institutional controls; and (5) on-going surface water and groundwater monitoring at the site.

The extraction and air stripping or carbon adsorption of groundwater are simply unnecessary for the protection of human health and the environment. EPA endorses Alternatives 5 and 6 to remediate a site that, by its own admission, "poses only a relatively low, long-term threat to human health and the environment". (Proposed Plan, p. 14). As pointed out in these Comments, even that low risk was grossly overestimated: EPA's Proposed Plan is based on both unrealistic, excessively cautious assumptions regarding the future likelihood that residents would ingest contaminated groundwater and risk calculations that rely on flawed methodology and outdated scientific theory.

For this future health risk to occur, either (1) persons would have to inhabit the property directly adjacent to the landfill and use the shallow groundwater aquifer as a source of drinking water; or (2) the plume of contamination would have to maintain its present concentration, migrate 2,000 feet downgradient from its present location, and affect private wells for 30 years. The fact is that currently, both the closest residence and drinking water well downgradient of the WRL site are

approximately 2,000 feet away. More importantly, that well has not been contaminated. In addition, for practical reasons such as area flooding problems, residential construction near the landfill is highly unlikely, and, even if houses were built in the area, there are readily available water supplies that could be utilized as alternatives to the contaminated shallow aquifer.

EPA's Proposed Plan is also based upon flawed and outdated scientific methodology used in calculating the risks. The cancer risk for the site is mainly premised on the future exposure of residents to arsenic and vinyl chloride. Yet even the highest level of arsenic ever detected in groundwater at the site is below the national primary drinking water standard of 50 ppb, which EPA and the National Academy of Sciences regard as adequately protective of human health. (FS, Table 3-2). Moreover, the calculated risk fails to take into account evidence that the human body detoxifies and excretes arsenic at any levels that might be ingested in the WRL area. Further, it incorporates cancer slope factors for arsenic and vinyl chloride that are both unreliable and unreasonable. In fact, the cancer slope factor required by EPA for arsenic is so unreasonable that, by its terms, drinking water with concentrations at the national primary drinking water standard level would pose severe risks to human health.

The non-cancer risk calculations for the site are equally unreliable. They are based on extremely high uncertainty values for 1,2-dichloroethenes and thallium, which represent about 50% of the non-cancer risk projected for the site. They are also based

on calculations in which contaminant-specific risk estimates were unnecessarily and improperly aggregated.

For all of these reasons, the Pagel's Pit Landfill Participating PRPs believe that Alternative 2, i.e., closure of the landfill in accordance with the WRL's operating permit, is adequately protective and should be adopted in EPA's Record of Decision. In addition to Alternative 2, the PRPs also support the implementation of institutional controls, i.e., new well and property development restrictions, although they may be overly cautious in protecting human health and the environment. Finally, in the event that EPA rejects both of these options, the PRPs urge EPA to select Preferred Alternative 6 (air stripping of groundwater) as it is equally protective but less expensive than Preferred Alternative 5 (carbon adsorption of groundwater).

I. SUMMARY OF THE RELEVANT FACTS AND PROCEEDINGS TO DATE

A. Description Of The Site

The WRL is an active land disposal site owned and operated by Winnebago Reclamation Service, Inc. ("WRS"). The landfill occupies approximately 40 acres of a 245 acre site located approximately five miles south of Rockford, Illinois in Winnebago County. It is bounded on the west by Killbuck Creek and on the east by Lindenwood Road. The site is situated immediately west and downgradient of the former Acme Solvents site, now a heavily contaminated and leaking Superfund site, that operated as an industrial waste disposal site without a permit from 1960 to 1973. Thorough descriptions of the site have been set forth in the

following study reports: Remedial Investigation Report For The Winnebago Reclamation Landfill, Rockford, Illinois (March, 1991) (the "Remedial Investigation Report" or "RI") and Feasibility Study For The Winnebago Reclamation Landfill, Rockford, Illinois (March, 1991) (the "Feasibility Study" or "FS"). Both of these reports were prepared by Warzyn Inc. ("Warzyn"), in compliance with applicable EPA guidelines, and instructions from EPA's Remedial Project Manager.

Land use around the site is a mix of industrial, agricultural, commercial, and rural residential. (RI, p. 1-6). The Rockford Skeet Club is located to the northeast of the site across Lindenwood Road. (Id.). A septic tank pumping business is located to the west, a private hunt club to the southwest, and a limestone quarry to the east of the site. (Id.). There are scattered residences within 1/2 of a mile of the site to the north, south, southwest, and southeast. (Id.). Of these residences, only one is located downgradient of the WRL site. (Id.).

The WRL was established in response to requests by the City of Rockford. It serves a number of valuable and necessary functions for the community. Since its inception in 1972, the WRL has been operating as a properly licensed solid waste disposal facility and has had a good record of environmental compliance and close cooperation with state and local authorities. The landfill has an estimated five to seven years of capacity remaining. (RI, p. 1-7).

The WRL has been operating with a state-of-the-art liner and leachate collection system as well as a landfill gas collection

system. Wastes accepted at the WRL site are composed primarily of municipal refuse and sewage treatment plant sludge. (Id.). A very limited amount of Illinois special non-municipal wastes were disposed at the facility prior to December, 1975, under permits issued by IEPA. (Id.). There is no direct evidence of any significant amounts of CERCLA hazardous substances emanating from this facility.

B. Placement Of The Site On The National Priorities List And Comments Submitted In Opposition To The Listing.

In October 1984, the WRL site was proposed to be included on EPA's National Priorities List ("NPL"). The proposed listing was premised on the erroneous theory that the WRL was leaking. According to that theory, a plume of groundwater contaminated with volatile organic chemicals ("VOCs") was flowing from the facility into the aquifer beneath it where it was interacting with the plume originating from the Acme Solvents NPL site, located due east and upgradient. In June 1986, the WRL site was placed on the NPL, despite WRS's extensive comments to EPA opposing the listing. (See WRS Comments Submitted To The United States EPA On Its Proposed Listing Of Pagel's Pit On The Superfund National Priorities List (December 14, 1984)).

The theory that the WRL liner has leaked significant amounts of CERCLA hazardous substances is still not supported by any direct evidence. As stated over six years ago in the comments opposing the WRL listing, a more plausible explanation for the presence of VOC contamination at the WRL site is that it migrated with the groundwater from the upgradient Acme Solvents site. Even

EPA in its Proposed Plan pointed out that "the highest concentrations of VOCs have been found in several wells on and close to the Acme Solvent site". (Proposed Plan, p. 4). Yet, despite extensive scientific evidence to the contrary, EPA continues to infer that the WRL constitutes a separate source of VOC contamination. A detailed discussion of the hydrogeologic evidence in the area is provided in Section 4 of the Remedial Investigation Report.

C. The Studies Of The Site

Before the WRL was placed on the NPL, extensive investigations had been conducted in the vicinity of the WRL and Acme Solvents sites. The results of those investigations were set forth in several reports which are listed in the Remedial Investigation Report for the WRL site. (See RI, p. 1-7).

After the WRL site was placed on the NPL, EPA and certain Pagel's Pit Landfill Participating PRPs, in October 1986, entered into an Administrative Order by Consent. Pursuant to the Order, the PRPs funded a Remedial Investigation Report and Feasibility Study (referenced in Section I.A. of these Comments), performed by the environmental engineering firm of Warzyn.[2] (Order, p. 9).

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[2] The remedial investigation performed at the WRL site was carried out in two phases. At the completion of Phase I of the remedial investigation, Warzyn prepared and submitted to EPA an Interim Groundwater Quality Evaluation Report (March, 1990) ("IGQE"). That report considered data collected from the previous investigations conducted before the WRL site was listed on the NPL. Phase II of the remedial investigation was performed based upon the recommendations presented in the IGQE and approved by EPA.

II. A COMPREHENSIVE STUDY OF THE WRL SITE CARRIED OUT BY HIGHLY QUALIFIED EXPERTS, UNDER THE DIRECTION OF AND IN CONSULTATION WITH EPA AND IEPA, HAS CONCLUDED THAT THE SITE POSES NO SIGNIFICANT RISK TO HUMAN HEALTH OR THE ENVIRONMENT.

In March, 1991, Warzyn published the results of its extensive investigation regarding the WRL site in their Remedial Investigation Report. As part of that report, Warzyn also completed a Baseline Risk Assessment ("BRA") in which the human health and environmental risks for both current and hypothetical future conditions at the WRL site were evaluated. (See RI, Section 6). The BRA assesses the presence, toxicity, environmental impact, and potential exposure pathways for over 50 chemicals of potential concern, and concludes that none of these substances currently pose a human health or environmental threat. However, Warzyn did find that several substances, including vinyl chloride, arsenic, 1,2-dichloroethenes, thallium, and zinc potentially pose some measure of concern to human health in the future. We believe that this finding was based on highly unrealistic assumptions regarding future exposure and on calculations that grossly overestimate the risks at the WRL site, which Warzyn was required by EPA to use.

A. Neither Health Nor Environmental Risks Have Been Identified For The Site Under Current Conditions.

In the BRA, Warzyn discussed the presence of substances in air, groundwater, food sources, sediment, and surface water at the WRL site. Based on extensive sampling data and laboratory analyses, Warzyn found that none of these media pose a human health or environmental threat under current site conditions. Specifically, VOC concentrations upwind and downwind of the WRL

site are very low, suggesting a de minimis level of VOC exposure to nearby residents, and concentrations of VOCs in ambient air are much lower than the safe exposure levels for workers. (RI, p. 6-14). Consequently, air was not considered a substantial pathway for chemical exposure.

The groundwater in the deep aquifer at and downgradient of the WRL site does not appear to be contaminated.[3] Although there is a contaminated groundwater plume in the shallow aquifer that has migrated approximately 900 feet downgradient of the site, the water within this area is not used for drinking. (RI, p. 6-14). In fact, there are no drinking water wells within 2,000 feet downgradient of the WRL site. (Id.). Because private drinking water supplies downgradient of the landfill are not contaminated, groundwater was not considered a source of chemical exposure. (Id.).

Fish were considered the most susceptible group of aquatic species subject to chemical exposure via contamination in Killbuck Creek. Based on the Ambient Water Quality Criteria, the BRA found that the chemical concentrations in the Creek's surface water will not have any adverse health effects on fish.[4] (RI, p. 6-50). Therefore, fish consumption was not considered a substantial pathway of chemical exposure. (RI, p. 6-15). In addition,

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[3] The Supplemental Technical Investigation Report For The Acme Solvents Site (May 29, 1990) ("STI") revealed that there was no VOC contamination within the St. Peter Sandstone aquifer, which is a regionally extensive aquifer underlying the Galena-Platteville shallow dolomite aquifer. (STI, p. 70).

[4] In addition, since the health of this most sensitive group of organisms is unimpaired, Warzyn concluded that other aquatic ecosystem effects are not anticipated. (RI, p. 6-50).

neither garden vegetables nor crops grown in the floodplain of Killbuck Creek were considered sources of chemical exposure since the majority of substances detected in groundwater, i.e., VOCs, do not readily bioaccumulate in plants. (RI, p. 6-16).

Sediment and surface water samples from Killbuck Creek indicate that leachate from the landfill is not impacting these media. Similarly, these media do not appear to have been affected by groundwater contamination, although a small amount of groundwater does discharge to the Creek. Because of this nominal discharge, surface water and sediment in Killbuck Creek were considered the only point of chemical exposure to persons under current site conditions. Currently, Killbuck Creek is not a source of public drinking water nor has it ever been used for that purpose.[5] (RI, p. 6-15).

Warzyn assumed that individuals at the Killbuck Bluffs Forest Preserve, a recreational area about 1.5 miles downstream of the WRL, might wade in the Creek and be exposed to sediment by incidental ingestion and dermal contact, and to surface water through dermal contact. (RI, p. 6-15). The risk of incidental ingestion is extremely low because the Creek is only one to two feet deep and there is no basis to believe that persons can swim there. (Id.). Assuming these exposure conditions, noncarcinogenic health effects are not expected. The cumulative non-cancer risk, or Hazard Index ("HI") under current site conditions, $HI=1x10^{-2}$, is far below the relevant threshold non-cancer

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[5] Source: Telephone conversation with Walter Purcell, Environmental Protection Engineer, IEPA Division of Public Water Supplies (May 8, 1991).

risk, i.e., HI=1. Similarly, the cumulative cancer risk, $6x10^{-7}$, is also well below EPA's target risk range for remediation at Superfund sites, i.e., $1x10^{-4}$ to $1x10^{-6}$, or a 1 in 10,000 to a 1 in 1,000,000 chance. (RI, p. 6-36).

Even these low risk calculations substantially overestimate the risk. First, they are based on the maximum concentration of each contaminant detected in sediment and surface water at Killbuck Creek. (RI, p. 6-36). Second, they are based on highly conservative assumptions regarding current site exposure conditions. For example, the calculations are based on sediment and surface water samples taken in the area of the Creek that is adjacent to the landfill. That area is owned by WRS and may not be accessed by the public. Killbuck Bluffs Forest Preserve, the location where children are presumed to wade in Creek, is 1.5 miles downstream of the landfill. (RI, p. 6-11) At this distance, contaminant concentrations would be significantly attenuated. Third, the risk calculations are based on exposure estimates for children rather than adults, which while not improper because there may be a child in the area at some point, do increase the risk.[6]

Further, most sediment is likely to wash off persons while they are wading so the potential for prolonged sediment contact is unlikely. (RI, p. 6-16). It is also highly unlikely that individuals wade in the Creek once a week for as long as eight months per year, as assumed in the BRA. The mean temperature in

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[6] An equivalent dose of a chemical is more toxic to a child than it is to an adult. (RI, p. 6-11).

Rockford, Illinois during March and April is 35° and 48° Fahrenheit, respectively, and 52° Fahrenheit during October.[7] The water temperature during those months is not much higher.[8]

B. The Proposed Plan Is Based On Unrealistic Assumptions And A Gross Overstatement Of The Future Risks At The Site.

1. **The Worst-Case, Future Exposure Scenario Is Completely Unrealistic.**

The health risks projected for the WRL site under the future exposure scenario are based on artificial, hypothetical assumptions. Under this scenario, it was assumed that contaminated groundwater with chemical concentrations equal to current concentrations, will be a source of exposure to residents living adjacent to and downgradient of the WRL site for 30 years.[9] For the future exposure scenario to be applicable, either (1) persons would have to inhabit the property directly adjacent to the landfill and use the shallow groundwater aquifer as a source of drinking water; or (2) the plume of contamination would have to maintain its present concentration, migrate 2,000 feet downgradient from its present location, and affect private wells for 30 years.

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7 Source: 1989 Local Climatological Data Annual Summary With Comparative Data; Rockford, Illinois - National Oceanic And Atmospheric Administration.

8 Source: U.S. Geologic Survey Water Resources Data, Illinois (1984-86; 1988).

9 According to EPA's Risk Assessment Guidance For Superfund, (December 1989), 30 years is the "reasonable worst case" assumption figure for residential time.

The fact is that WRS owns all of the property surrounding the landfill, and a substantial amount of adjacent property. Currently, the closest residence located downgradient of the WRL site is approximately 2,000 feet away. More importantly, the closest downgradient drinking water well (PW1 or PW0), which is also 2,000 feet from the WRL site, is not contaminated. Further, residential construction near the landfill is highly unlikely because of area flooding problems. Even if houses were built near the WRL site, drinking water would not have to be drawn from the shallow aquifer as there are readily available alternative water supplies from the deep aquifer in the area. (RI, p. 6-14).

The property downgradient of groundwater flow from the WRL site consists of heavily vegetated land and a 100-year floodplain. (RI, p. 6-18). Houses built within the floodplain must comply with several burdensome conditions. For example, they must be built on piers that raise the lowest portion of the structures above the floodplain. (RI, p. 6-18). In addition, septic systems may not be placed in the floodplain and the nearest downgradient area located outside of the floodplain is 1,000 feet away from the WRL site. (RI, p. 6-18). Because of these practical considerations, it is therefore unlikely that houses will be built within 1,000 feet downgradient of the landfill, as assumed under the future exposure scenario.

The future exposure scenario also assumes the use of contaminated aquifer water for drinking purposes. Two key facts reveal the flaws in this assumption. First, new well construction plans must be approved by the Winnebago County Health Department, which

can both discourage (or prohibit) the installation of water supply wells in areas of known contamination and condemn wells if contamination would be a health concern. (RI, p. 6-18). Second, there are readily available alternative water supplies that are much better as to quality in the area. In fact, the recent Record of Decision for the Acme Solvents site (December, 1990) provides for the construction and installation of a public water supply system serving the area. Moreover, as noted above, a deeper uncontaminated aquifer extends throughout the area. Based on these factors, it is highly unlikely that wells for drinking water will be constructed directly adjacent to and downgradient of the site.

In the future, it is highly improbable that existing private drinking water wells will be affected by groundwater contamination associated with the landfill. The distance to the nearest downgradient well is approximately 2,000 feet, and groundwater contamination is attenuated within approximately 900 feet downgradient of the site. (RI, p. 6-21). Future groundwater contamination will be further curtailed as the landfill ages and chemical concentrations decrease. In addition, much of the groundwater risk due to non-cancer effects are associated with less mobile contaminants such as thallium and zinc. These metals will migrate only a short distance from the site because of adsorption and precipitation in the aquifer. (RI, p. 6-39). Moreover, while more mobile than metals, VOCs such as dichloroethenes and vinyl chloride naturally attenuate through biodegradation and dispersion in groundwater.

Finally, as with risk calculations for exposure to surface water and sediment under current site conditions, calculations for future site risks are based on highly conservative assumptions. Namely, the 30 year residential period used in calculating future exposure risks is considered the worst-case, maximum period during which a resident near the WRL would be exposed to groundwater. Indeed, in the United States, most people live at a given residence for less than 30 years. (Exposure Factors Handbook; EPA, July 1989). Moreover, the risk calculations are based on a worst-case estimate of the contaminant concentrations presently in groundwater near the site.[10] (RI, p. 6-24).

2. The Cancer Risk Calculations For The Site Are Contrary To Common Sense And Good Science.

Considering the unrealistic assumptions upon which the worst-case future exposure scenario is based, it is not surprising that a cancer risk of $1x10^{-3}$ has been identified. (See RI, p. 6-38). The cancer risk is mainly premised on the hypothetical exposure of residents to arsenic and vinyl chloride through ingestion of groundwater and dermal contact or inhalation while bathing. (Id.). That risk defies common sense: even the highest level of arsenic ever detected in groundwater at the site is below the national primary drinking water standard of 50 ppb, which EPA

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[10] The 95% upper-bound confidence limit ("UBCL") or maximum concentration was used to characterize exposure point concentrations for each chemical of potential concern in groundwater. Maximum concentrations were used when the 95% UBCL was greater than the maximum values. Using these contaminant concentrations, the calculated risks represent a worst-case estimate of exposure point chemical concentrations. (RI, p. 6-24).

and the National Academy of Sciences regard as adequately protective of human health. (FS, Table 3-2). Moreover, the cancer risk identified from exposure to arsenic is based on scientifically flawed methodology. That risk fails to take into account evidence that the human body detoxifies and excretes arsenic at levels that might be ingested in the WRL area. It also incorporates a cancer slope factor for arsenic that is so unreasonable that, by its terms, drinking water with concentrations at the national primary drinking water standard level would pose severe risks to human health. The cancer slope factor required by EPA for vinyl chloride is equally unreasonable.

a. Humans Effectively Detoxify And Excrete Arsenic That Is Ingested At Or Below The Rate Of 250 Micrograms Per Day, Which Critically Affects The Risk Assessment For This Site.

In calculating the cancer risk from hypothetical arsenic exposure, the BRA failed to consider the fact that at low doses (less than 250 ug/day), 80-90% of ingested and absorbed arsenic is detoxified and excreted efficiently. This natural detoxification process has been documented by scientific studies and has been officially recognized by EPA's Science Advisory Board ("SAB") in a report submitted to EPA Administrator William K. Reilly, on September 28, 1989. The report addresses the potential carcinogenicity of arsenic in the context of drinking water standards. A copy of that report is attached hereto as Attachment A.

One of the points addressed in the SAB Report was the evidence that small amounts of arsenic are or may be an "essential

nutrient" for humans. The report left that issue unresolved. It stated:

> Admittedly, numerous studies in laboratory and domestic animals have suggested the essentiality of arsenic in some of those species; however, the evidence is not sufficiently persuasive to conclude unequivocally that arsenic is essential for normal health, growth or reproduction. (SAB Report, p. 1).

More importantly, the report was quite clear on the detoxification of arsenic ingested by humans. On the subject of carcinogenicity generally, the report resolved any uncertainties in favor of protectiveness, and adopted the position that "arsenic ingested at high doses can cause cancer in humans" -- specifically, skin cancer. (SAB Report, p. 3). The authors stated, however, that at lower doses (such as ingestion through drinking water), the ability of arsenic to cause cancer has simply not been demonstrated:

> The risk of cancer at doses encountered in U.S. tap water has not been empirically determined. (SAB Report, p. 3).

The report acknowledged that this may be a possibility, but added:

> This depends in part on the ability of the human body to efficiently detoxify relatively small doses of ingested arsenic. Convincing evidence of human metabolism of ingested inorganic arsenic has been presented by the EPA. . . . Specifically, conversion by the liver of inorganic arsenic by methylation to monomethylarsenic acid (MMA) and to dimethylarsenic acid (DMA) is the predominent pathway of detoxification in humans. The findings indicate that daily doses of 250-1000 ug [micrograms] As^{3+}/person/day or less may be largely detoxified. . . . The risk of cancer induction at lower levels of intake are then likely to be greatly exaggerated if the

> relevant pharmacokinetic considerations are not appropriately taken into account. (SAB Report, pp. 3-4).

The SAB Report then noted that the detoxification at these dose levels appears to be 80-90% complete based on their review of the data. Thus, there is some residual exposure (10-20%) that should be considered:

> However, because the detoxification at lower doses does not appear to be more than 80-90% complete, the possibility of some risks at lower doses cannot be ignored. The Subcommittee concludes that the metabolic evidence for at least partial detoxification is sufficiently persuasive to incorporate it directly into the derivation of an MCL [maximum contaminant level, or drinking water standard], with appropriate consideration of the known heterogenicity of detoxification in the human population. (Id., p. 4).

EPA and Warzyn in their BRA failed to consider this 80-90% detoxification factor. The SAB report should be relied on by EPA Region V in this case as representing the most current and reliable scientific position by the Agency on this subject. The SAB's data show that only 10-20% of arsenic absorbed would be in a form that is of carcinogenic significance. That data is applicable to this site because total daily intake of arsenic by site residents from ingestion of groundwater is estimated to be only 16.8 micrograms,[11] which is well below the 250 microgram per day threshold described by the SAB.

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[11] $\frac{2\ L\ groundwater}{day\ (1)} \times \frac{8.4 \times 10^{-3} mg}{L\ (2)} \times \frac{1 \times 10^{3} ug}{mg} = 16.8\ ug/day$

(1) RI, p. 6-29
(2) RI, Table 6-14

The BRA should have concluded that arsenic concentrations in the groundwater at the site are not above the acceptable risk range for remediation at Superfund sites. Based on that, EPA in its Proposed Plan would not have concluded that there was a need to undertake groundwater remediation because of arsenic.

b. EPA's Assumptions About The Carcinogenic Potential Of Arsenic Are Grossly Overstated; Exposures To Arsenic At This Site Pose Significantly Less Risk Than Drinking Water Where The Arsenic Concentration Is At The National Primary Standard Under The Safe Drinking Water Act.

A second aspect in which the BRA significantly overstated the actual risks associated with future exposure to groundwater was in applying EPA's cancer slope factor[12] (also referred to as "cancer potency factor") for arsenic of 1.8 (mg/kg/day)$^{-1}$. (See RI, Table 6-11). Warzyn in conducting the BRA was obliged to use this cancer slope factor as a matter of EPA policy. This cancer slope factor has been called into serious question as being vastly overprotective. It is based on epidemiological data from a study (Tseng et al., 1977)[13] conducted in Taiwan which has been subjected to widespread criticism in the scientific community. Though EPA's SAB has apparently concluded that the study can be relied on to the limited extent of indicating that arsenic is a potential carcinogen by ingestion, the SAB has noted

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12 A cancer slope factor is a value developed by EPA used to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen. (EPA's Risk Assessment Guidance for Superfund, p. 8-2).

13 The Tseng study is discussed in more detail in the attached SAB Report.

that there are significant distinctions between the Taiwanese populations and the U.S. populations, and further noted that "the few epidemiological investigations carried out in the U.S. failed to find any such association" (i.e., between arsenic in drinking water and cancer). It concluded that use of the Taiwanese study as the basis of a cancer slope factor results in "overestimating cancer risk from the relatively high doses of ingested arsenic" that the Taiwanese population received. However, that is exactly what was done by EPA earlier in arriving at its cancer slope factor.

EPA calculated its cancer slope factor for ingested inorganic arsenic using the linear-quadratic model fit to the Tseng et al. Taiwanese data. The Drinking Water Subcommittee of EPA's SAB, however, has recommended that a revised risk assessment be developed utilizing a non-linear dose-response relationship for skin cancer associated with estimates of the effective delivered dose of non-detoxified arsenic to target tissues.

The application of EPA's existing cancer slope factor to a person who drinks water containing arsenic at 50 ppb yields an incremental risk of one in four hundred.[14] This risk is higher than the cumulative cancer risk projected in the BRA, which is one in one thousand. The fault is not with the 50 ppb standard, but with the overly conservative assumptions used by EPA in devising its cancer slope factor.

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[14] This is based on consumption of two liters per day, which is the value typically used.

Thus, EPA's use of a cancer slope factor for arsenic of 1.8 $(mg/kg/day)^{-1}$ grossly overstates any risk of cancer from arsenic. Use of this cancer slope factor projects an assumed hypothetical risk level which is rebutted by more reliable and extensive epidemiological data showing that populations consuming drinking water over the long-term with substantial concentrations of arsenic should be suffering major illness if the arsenic cancer slope factor were used, yet in fact they are not.[15] The existence of this phenomenon corroborates the soundness and the reality of the detoxification factor discussed by the SAB and documented in the studies they reviewed. It provides strong support for the use by EPA of that detoxification factor in calculating risk in this case.

c. EPA's Assumptions About The Carcinogenic Potential Of Vinyl Chloride Are Overstated.

The BRA also overstated the actual risks associated with future exposure to groundwater in applying EPA's required cancer slope factor of 2.3 $(mg/kg/day)^{-1}$ for ingestion of vinyl chloride. (See RI, Table 6-11). This cancer slope factor is unreasonably conservative and highly unreliable. Unlike arsenic, it is not even based on epidemiological (human) data; rather, it is based on laboratory studies on rats. (See RI, Table 6-10).

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15 In three epidemiological studies conducted in the United States (Southwick et al., 1981; Harrington et al., 1978; and Morton et al., 1976), investigators found no positive relationship between arsenic levels in drinking water and adverse effects. Exposure levels in these studies were as high as 224 ppb, which is more than four times the EPA national drinking water standard of 50 ppb.

The value of animal studies in predicting cancer in humans has been called into serious question, especially as to quantitative dose extrapolation. During such testing, extremely high doses of chemicals are administered to laboratory animals. For chemicals which seem to cause or increase cancer, the results of these high-dose animal studies are then extrapolated to the low-dose human exposure situation using artificial mathematical models. It is obvious that under these conditions, the fact that a chemical is a carcinogen in rats does not provide much, if any, evidence about low-dose cancer risks (such as that projected for the WRL site) to humans. (See Ames and Gold, Too Many Rodent Carcinogens: Mitogenesis Increases Mutagenesis, 249 Science 970 (August 31, 1990), which is attached hereto as Attachment B).

Clearly, laboratory studies based on animal to human extrapolation yield highly uncertain results. (RI, p. 6-34, 6-44). This uncertainty is inherent in the cancer slope factor for vinyl chloride used in assessing the cancer risk at the WRL site. (RI, p. 6-44).

In addition, while the source of vinyl chloride contamination may not be particularly relevant to the effects of the contamination itself, the Pagel's Pit Landfill PRPs do point out that vinyl chloride is a biodegradation product of precisely those solvents, i.e., tetrachloroethene (PCE), trichloroethene (TCE), and 1,1 and 1,2-dichloroethenes (DCE), that were disposed of at the Acme Solvents site and detected in wells between the WRL and Acme Solvents sites. (RI, pp. 4-40 to 4-45). Therefore, any discussion of the hydrogeology in the WRL area that EPA decides to

include in the Record of Decision must recognize this fact. (See Section 4 of the Remedial Investigation Report for a detailed discussion of groundwater releases from the Acme Solvents site and their degradation products).

3. The Non-cancer Risk Calculations Are Overstated And Have Limited Value.

The non-cancer risk of five (Hazard Index or "HI"=5) calculated for the WRL site is mainly premised on the hypothetical exposure to 1,2-dicholorethenes, thallium, and zinc through ingestion of groundwater and dermal contact or inhalation while bathing. (RI, p. 6-37). If cobalt were not completely discounted by EPA, then the non-cancer risk would have been twenty times higher, i.e., HI=100. EPA in its Proposed Plan did, however, concede that cobalt was found in only one well at the site and that the level of cobalt detected was based on an interim reference dose. (Proposed Plan, p. 5). That dose is less than a person's normal daily intake of cobalt.

The arbitrariness of the future non-cancer risk calculations for the site is graphically illustrated by this result. These calculations are also unreliable because they are based on extremely high uncertainty values as well as calculations where contaminant-specific risk estimates were unnecessarily and improperly aggregated.

a. The Calculations Of Hypothetical Non-cancer Risks Are Based On Extremely High Uncertainty Factors Associated With The Toxicity Values For 1,2-Dichloroethenes And Thallium.

A significant portion of the non-cancer health risk associated with groundwater ingestion is attributable to 1,2-dichloroethenes (26%) and thallium (22%). (RI, p. 6-43). EPA has assigned high uncertainty factors to the toxicity values (RFDs) developed for evaluating the noncarcinogenic effects of those substances.[16] This high uncertainty is attributable, in part, to the uncertainty of extrapolating from animal test data (rat and mice studies) to humans. (RI, p. 6-44 and Table 6-10). As noted in EPA's Risk Assessment Guidance for Superfund (December, 1989), high uncertainty corresponds with low confidence or weak evidence, which indicates that the toxicity values for 1,2-dichloroethenes and thallium are likely to be altered as soon as better toxicity data becomes available. Because it relies so heavily on such highly uncertain toxicity values, EPA should discount that portion of the non-cancer risk attributable to these substances.

b. By Aggregating The Contaminant-Specific Risk Estimates/ Hazard Quotients For 1,2-Dichloroethenes, Thallium, And Zinc, The Non-cancer Risk At The Site Was Improperly Overestimated.

The individual non-cancer risk estimates for 1,2-dichloroethenes, thallium, and zinc are low. The Hazard Quotient

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Substance	Uncertainty Factor
1,2-dichloroethene (cis)	3,000
1,2-dichloroethene (trans)	100
thallium	3,000

Source: RI, Table 6-10.

("HQ"), a calculation used to estimate the risk due to a noncarcinogenic chemical, for each of these substances is equal to 1. (RI, p. 6-33; 6-38). This indicates that noncarcinogenic health effects from exposure to any one of these substances alone would not be expected. (RI, p. 6-38). In an attempt to be conservative in calculating the risk, however, Warzyn in the BRA added these contaminant-specific risk estimates (Hazard Quotients) to reach a Hazard Index (the sum of the Hazard Quotients) of 5. (RI, p. 6-44). Warzyn aggregated the risks because it assumed the possibility of additivity between chemicals. (Id.). Warzyn in the BRA cautioned that it is equally possible that "no toxicological interaction between chemicals exist" and advised that "a certain conclusion cannot be drawn because of the limited toxicological information on the interactions of these chemicals when ingested in combination". (Id.).

The BRA needlessly overestimated the non-cancer risk by aggregating the Hazard Quotients for thallium with those for 1,2-dichloroethenes and zinc. Thallium affects the hair follicles; 1,2-dichloroethenes and zinc affect the blood. (RI, p. 6-38). According to EPA's Risk Assessment Guidance, risk estimates generally should not be combined for contaminants that do not affect the same organ. (RAG, p. 8-14). Warzyn discusses this principle in the BRA:

> As exposure to these chemicals may occur simultaneously, there is a greater potential that the combined exposure to these chemicals may result in non-cancer health effects. This would generally occur if the chemicals affect the same target organ. (RI, p. 6-38) (emphasis added).

Had the Hazard Quotient of 1 for thallium not been added with the Hazard Quotients for 1,2-dichloroethenes and zinc, the Hazard Index, i.e., non-cancer risk for the site, would have been reduced by 20%.

III. EPA SHOULD ADOPT REMEDIAL ACTION ALTERNATIVE 2 -- PLANNED CLOSURE -- IN THE RECORD OF DECISION FOR THIS SITE.

A. Planned Closure Would Adequately Protect Human Health And The Environment.

EPA, in its Proposed Plan, erroneously concludes that Alternative 2, planned closure of the landfill, "would not provide adequate protection of human health and the environment" because it does "not include groundwater extraction and treatment". (Proposed Plan, p. 12). This conclusion has no merit. Under Alternative 2, the site would be closed according to the landfill's operating permit. (FS, p. 3-14).

Upon proper closure of the landfill, a highly reliable cap, compliant with the stringent, recently revised Illinois municipal landfill regulations, would be placed over the wastes. The cap would reduce the volume of precipitation reaching the landfill and minimize the volume of leachate generated. (FS, p. 3-16). The cap would also minimize the potential for contaminants to migrate off-site via surface water runoff. Moreover, the landfill's existing gas extraction system would be upgraded to prevent landfill gas from migrating off-site. The landfill's existing leachate extraction system would continue to reduce the migration of contaminants to groundwater. Leachate treatment at the POTW

would effectively destroy or remove contaminants from the waste stream. Finally, post-closure groundwater and surface water monitoring as well as maintenance of the landfill cap, leachate extraction system, and gas collection system would be implemented under this alternative. (FS, pp. 3-16, 4-8). To further ensure the protectiveness of this alternative, a periodic review of the site would be conducted at least every five years, as required by Superfund. (FS, p. 4-9).

B. Compliance With Applicable Or Relevant And Appropriate Requirements (ARARs) Will Be Satisfied.

EPA also indicates in its Proposed Plan that Alternative 2 would not be able to meet the identified applicable or relevant and appropriate requirements (ARARs) because it "leave[s] contaminated groundwater in place allowing it to continue to move away from the site". (Proposed Plan, p. 12). While it is true that Alternative 2 does not include groundwater extraction and treatment, EPA fails to acknowledge that there is a long implementation period associated with such treatment. Moreover, despite the fact that groundwater extraction and treatment has been implemented at Superfund sites for over 10 years, there has been ongoing scientific debate over the treatment's effectiveness.

Under Alternative 2, the source of groundwater contamination, i.e., landfill wastes and leachate, would be contained. Substances currently in the groundwater would be reduced by natural attenuation mechanisms, i.e., through biodegradation and dispersion. The fact that groundwater contamination is presently

attenuated within approximately 900 feet downgradient of the site provides concrete evidence that this natural process is working.

These facts support a waiver of compliance with ARARs pursuant to Superfund Section 121(d)(4)(C), which expressly permits a waiver where "compliance with such requirements is technically impracticable from an engineering perspective". They also support such a waiver pursuant to Section (D), which allows such a waiver where "the remedial action selected [in this case planned closure] will attain a standard of performance that is equivalent to that required under the otherwise applicable standard, requirement, criteria, or limitation, through use of another method or approach". Thus, the alternative that the Pagel's Pit Landfill Participating PRPs recommend in these Comments is consistent with the remedial requirements of Superfund.

IV. TO ENSURE THAT A "WORST-CASE FUTURE EXPOSURE SCENARIO" DOES NOT OCCUR, THE ADOPTION OF INSTITUTIONAL CONTROLS, INCLUDING NEW WELL AND PROPERTY DEVELOPMENT RESTRICTIONS, MAY BE APPROPRIATE IN ADDITION TO REMEDIAL ACTION ALTERNATIVE 2.

Although institutional controls, through new well and property development restrictions, may reflect an overabundance of caution, the Pagel's Pit Landfill Participating PRPs support them in addition to Alternative 2 as reasonable measures to eliminate potential future risks to long-term residents in the area. In Section 2 of the Feasibility Study, Warzyn conducted a detailed identification, screening, and evaluation of potentially applicable remedial measures, including the use of institutional controls. Both restrictions on new well development in

contaminated zones and deed restrictions for property development were considered in the study. (FS, p. 2-20).

Restrictions on new well development would prevent residents from exposure to contaminated groundwater and would be appropriate for properties within contaminated and potentially contaminated areas. (FS, p. 2-20). These restrictions would apply to contaminated zones of the shallow aquifer. As indicated in Section II.B. of these Comments, there are readily available alternative water supplies in the WRL area that would facilitate the implementation of these restrictions. For example, EPA's Record of Decision for the Acme Solvents site provides for the construction and installation of a public water supply system to serve residents with contaminated wells. In fact, EPA identifies a deep well located on the WRL site as a potential source for that system. (ROD, p. 28).

Similarly, deed restrictions for property development on and adjacent to the landfill would prevent exposure of residents to contaminated groundwater. The implementation of such restrictions should be feasible since WRS owns all of the land surrounding the landfill, much of the land adjacent to the landfill, and plans to purchase additional property in the area. As noted in the Feasibility Study, existing physical barriers such as fences, steep slopes, heavy woods, and Killbuck Creek are other measures that would restrict access to the WRL site. (FS, p. 3-18).

V. IF EPA NEVERTHELESS FAILS TO ADOPT ALTERNATIVE 2, OR ALTERNATIVE 2 WITH INSTITUTIONAL CONTROLS, THEN REMEDIAL ACTION ALTERNATIVE 6 -- AIR STRIPPING -- SHOULD BE ADOPTED IN THE RECORD OF DECISION FOR THIS SITE.

The Preferred Alternatives for remedial action prescribed in EPA's Proposed Plan, Alternatives 5 and 6, call for, among other things, air stripping or carbon adsorption of groundwater, respectively. (Proposed Plan, p. 14). Both alternatives also provide for: (1) capping the landfill in accordance with recently revised IEPA regulations; (2) upgrading the landfill's existing gas collection and leachate extraction systems; (3) extracting and transporting the leachate to the POTW for treatment; (4) institutional controls; and (5) on-going surface water and groundwater monitoring. (FS, pp. 3-31; 3-25). These measures are simply unnecessary for the protection of human health and the environment.

EPA endorses Alternatives 5 and 6 to remediate the WRL site, which it concedes "poses only a relatively low, long-term threat to human health and the environment". (Proposed Plan, p. 14). As pointed out in Section II of these Comments, that low risk was actually overestimated as a result of unrealistic, excessively cautious assumptions, relating primarily to the future likelihood that residents would ingest contaminated groundwater for 30 years, as well as flawed and outdated scientific methodology used in calculating the risks.

We believe that Alternative 2 -- planned closure -- with or without institutional controls, would be protective of human

health, and, therefore, an appropriate remedy for the site. Nevertheless, if EPA fails to adopt these alternatives, then the Agency should adopt Alternative 6 -- air stripping of groundwater -- in its Record of Decision. One of the most important conclusions of the Feasibility Study, which is reflected in EPA's Proposed Plan, is that Alternative 6 would in fact achieve each of EPA's nine criteria used to evaluate remedial action alternatives. (FS, pp. 4-21 to 4-24). Specifically, EPA in its Proposed Plan indicates that Alternative 6 "provides a good balance with respect to the evaluation criteria". (Proposed Plan, p. 14).

But for the method of groundwater treatment, EPA's Preferred Alternatives 5 (carbon adsorption of groundwater) and 6 (air stripping of groundwater) are identical. More importantly, both alternatives are equally effective so implementation of Alternative 5 would not result in a further reduction of the risk. In evaluating these Preferred Alternatives, EPA states:

> U.S. EPA and IEPA have determined that either of the preferred alternatives would protect human health and the environment, would comply with ARARs, would be cost effective, and would use permanent solutions and alternative treatment technologies to the maximum extent practicable. (Proposed Plan, p. 14).

Finally, implementation of Alternative 5 instead of Alternative 6 would add approximately $1.2 million to the cost. We believe that there is no useful purpose in spending more money to go beyond what achieves EPA's remedial objectives.

VI. EPA INCORRECTLY DESCRIBES THE RELATIONSHIP BETWEEN GROUNDWATER CONTAMINATION AT THE WRL AND ACME SOLVENTS SITES.

With respect to the contamination between the WRL and Acme Solvents site, EPA in its Proposed Plan asserts the following:

> a connection has not been established between the contamination on and near the Acme Solvent site and the contamination in the southeast corner of the Pagel's Pit site, since wells between these two areas either contained no VOCs or contained VOCs at concentrations much lower than those in these two areas. (Proposed Plan, p. 4).

EPA is wrong. That is precisely the claim that some of the Acme Solvents PRPs have been attempting to make, but it is belied by the hydrogeologic evidence.

As stated in our comments submitted to EPA on February 8, 1991, in response to the Record of Decision for the Acme Solvents site, measurable levels of VOCs have been found in samples from nine monitoring wells between the WRL and Acme Solvents sites. These samples indicate the presence of significant levels of VOCs upgradient of the WRL between the area south of the WRL site and west of Lindenwood Road and at well B4 at the Acme Solvents site. Monitoring well data gathered during the remedial investigation, and earlier, demonstrate that the majority of VOCs present in the area of the WRL are the same types of VOCs that were disposed of in the 1960's and early 1970's, at the Acme Solvents site, and their degradation products.[17] The naturally flowing groundwater from east (Acme Solvents site) to west (the WRL site) has transported these substances to the WRL area and beyond.

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[17] A thorough discussion of this data is set forth in Section 4 of the Remedial Investigation Report.

In the spring of 1990, the Acme Solvents PRPs had three additional wells installed in the area between the two sites. The sampling results from these wells were presented in the Northwest Area Investigation At The Acme Solvents Site (October, 1990) ("NAI") performed by Harding Lawson Associates. The groundwater data from two of the three wells show that VOCs are present in the area.[18] This data provides further evidence that Acme Solvents is the sole source of VOCs in groundwater between the two sites.

EPA also speculates in its Proposed Plan that the WRL chloride leachate plume "probably [extends] back to some of the southeast area of the site". (Proposed Plan, p. 4). Such speculation is unfounded. The Remedial Investigation Report for the WRL site clearly shows that the leachate plume, which is characterized by elevated chloride levels,[19] is limited to the northwest quadrant of the WRL site, the vicinity of wells G110 and G114, and the vicinity of well G115. (RI, p. 4-34). There is simply no evidence that the WRL leachate plume extends to the southeastern boundary of the WRL site.

Finally, EPA in its Proposed Plan (p. 12) states that if RCRA wastes have contaminated groundwater at the WRL site, then RCRA

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18 In particular, VOCs at concentrations of 1,349 ug/l in the sample from well STI-6S (located northeast of well B7) and 14.9 ug/l in the sample from well STI-71 (nested with well B9) were detected. (NAI, Figure 5.1).

19 As discussed in Section 4 of the Remedial Investigation Report for the WRL site, chlorides can be used to discriminate between WRL leachate-affected wells and unaffected wells, i.e., elevated chlorides are a reliable tracer of WRL leachate. (See RI, pp. 4-13 to 4-32).

ARARs would apply to the remediation of the groundwater. According to EPA, "[t]his also means that any residue from the treatment of this groundwater would be a listed waste under RCRA and would have to be treated accordingly". (Id.).

There is no evidence indicating that the WRL has received any RCRA wastes. The WRL site has accepted only municipal waste and limited quantities of Illinois special wastes. In contrast, Acme Solvents primarily disposed of hazardous materials, including VOCs, by pouring liquid solvents and sludges into unlined lagoons having direct access to groundwater. Since the Acme Solvents site is located upgradient from the WRL site, strong downward groundwater gradients beneath Acme Solvents allow for downward movement of contaminants from that site within the groundwater system.

The only RCRA wastes that could have contaminated the groundwater in the WRL area were those disposed of at the Acme Solvents facility. While it is not the proper function of the Proposed Plan or Record of Decision to discuss liability issues, the hydrogeologic evidence is relevant, and any statements by EPA on this subject must be consistent with the evidence set forth above and in the referenced reports and analyses.[20]

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[20] Consequently, the Pagel's Pit Landfill Participating PRPs expect the Acme Solvents' PRPs to substantially fund any remedial measures that may be required in the areas of the WRL site attributable to spent solvents or any other substances originating from the Acme Solvents site.

VII. CONCLUSION

Fortunately, the WRL site does not currently pose any threat of harm to human health or the environment. Although Warzyn concluded that the site may pose a nominal health risk under worst-case future conditions, this projected risk is based on unrealistic and excessively cautious assumptions required by EPA as well as flawed methodology and outdated scientific theory.

For these and the other reasons set forth in these Comments, the Pagel's Pit Landfill Participating PRPs urge that EPA adopt Alternative 2 (planned closure) in its Record of Decision for the WRL site. The PRPs also support the implementation of institutional controls, although this may reflect an abundance of caution in protecting human health and the environment. If EPA nevertheless rejects both of these options, EPA should select Preferred Alternative 6 (air stripping of groundwater) as it is equally protective but less expensive than Preferred Alternative 5 (carbon adsorption of groundwater).

The Pagel's Pit Landfill Participating PRPs appreciate the opportunity to submit these Comments in response to EPA's Proposed Plan for the site. We would be happy to discuss any aspect of these Comments or the Proposed Plan with EPA. We look forward to working with EPA, the State of Illinois, Winnebago County authorities, and local residents in making sure that remedial action at the WRL site is carried out in a way that provides

appropriate and adequate protection for human health and the environment.

Respectfully Submitted,

By _____

Pagel's Pit Landfill
Steering Committee:

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May 15, 1991

cc: MaryAnn LaFaire
Community Relations Coordinator
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ATTACHMENT A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D C 20460

EPA-SAB-EHC-89-038

September 28, 1989

OFFICE OF THE ADMINISTRATOR

Honorable William K. Reilly
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Subject: Science Advisory Board's review of the ARSENIC issues relating to the Phase II proposed regulations from the Office of Drinking Water.

Dear Mr. Reilly:

The Drinking Water Subcommittee of the Science Advisory Board's Environmental Health Committee has completed its review of the arsenic related issues identified in the Phase II proposed regulations from the Office of Drinking Water at its meeting in Cincinnati, Ohio, June 2-3, 1988.

The major recommendations of the Subcommittee are limited to a few specific areas concerning the health effects of arsenic and include the following: (1) that the evidence for the essentiality of arsenic is suggestive but should be excluded in characterizing health risks or in the development of a drinking water standard; (2) that the current state of scientific knowledge cannot resolve the important question of whether or not hyperkeratosis is a precursor of skin cancer and, thus, in establishing the MCL should consider hyperkeratosis and skin cancer as independent effects; (3) that the findings of the Tseng study are adequate to conclude that ingested arsenic can cause cancer in humans; and (4) that at dose levels below 200 to 250 ug As^{3+}/person/day there is a possible detoxification mechanism that may substantially reduce cancer risk from the levels EPA has calculated using linear-quadratic model fit to the Tseng data. We recommend that EPA (1) develop a revised risk assessment based on estimates of the delivered dose of non-detoxified arsenic to target tissues, and (2) consider the potential reduction in cancer risk due to detoxification in establishing an MCL for arsenic.

We appreciate the opportunity to conduct this particular scientific review. We request that the Agency formally respond to the scientific advice provided herein.

Sincerely,

Raymond C. Loehr
Chairman, Executive Committee

Arthur C. Upton
Chairman
Environmental Health Committee

Gary P. Carlson
Chairman
Drinking Water Subcommittee

ARSENIC

The Drinking Water Subcommittee of the Science Advisory Board's Environmental Health Committee met June 2-3, 1988 in Cincinnati, Ohio to review selected issues relating to the scientific background for regulating arsenic in drinking water. The Subcommittee concluded that; the evidence for essentiality is suggestive, that the current state of knowledge cannot resolve whether or not hyperkeratosis is a precursor of skin cancer and that at dose levels below 200 to 250 up As^{+3}/person/day there is a possible detoxification mechanism that may substantially reduce cancer risk. The Subcommittee recommended that EPA; develop a revised risk assessment based on estimates of the delivered dose of non-detoxified arsenic to target tissues, and consider the potential reduction in cancer risk due to detoxification in establishing a maximum contaminant level for arsenic.

SUBJECT: SCIENCE ADVISORY BOARD'S REVIEW OF THE ISSUES RELATING TO ARSENIC CONTAINED IN THE PHASE II PROPOSED REGULATIONS FROM THE OFFICE OF DRINKING WATER

SCIENCE ADVISORY BOARD COMMITTEE: DRINKING WATER SUBCOMMITTEE OF THE ENVIRONMENTAL HEALTH COMMITTEE

DATE OF REVIEW: JUNE 2-3, 1988

PLACE OF REVIEW: EPA LABORATORY, CINCINNATI, OHIO

A. Nutritional essentiality of arsenic

Whether arsenic is an essential nutrient for humans has been a topic of extensive scientific investigation; and for the present, the issue remains unresolved. Admittedly numerous studies in laboratory and domestic animals have suggested the essentiality of arsenic in some of those species; however, the evidence is not sufficiently persuasive to conclude unequivocally that arsenic is essential for normal health, growth, or reproduction. The body of evidence exploring such a role for arsenic in humans is much more sparse and far less convincing than for animals. Consequently, the Subcommittee concludes that arsenic cannot now be accorded the role of essential trace element for humans. Hence, for EPA's evaluation of health risks from small quantities of arsenic in tap water, attributing a prominent role to the essentiality of arsenic in human nutrition is unfounded. We recommend that the document be revised to acknowledge the existence of suggestive evidence but exclude the concept of essentiality as a factor in characterizing, or modulating, conclusions about health risk -- and, further, as a factor in establishing drinking water standards.

B. Hyperkeratosis

In some epidemiologic studies arsenic exposures were associated with skin lesions including cancer and hyperkeratosis. Unknown at present is whether hyperkeratosis elicited by inorganic arsenic is a lesion independent of the initiation of skin tumors or a step necessary in tumor formation. The distinction is important in assessing the risks from arsenic exposures in the following way: If hyperkeratosis were independent of skin cancer in the same individuals, there might continue to be a suitable justification for assuming that the dose-response curve for cancer would have no true threshold, and the data would be extrapolated toward zero dose/zero effect. On the other hand, if hyperkeratosis -- a lesion for which a threshold is not only plausible but also known -- were an obligatory intermediate to skin tumor formation, then the threshold for the first becomes the threshold for the second, leading to an extrapolation of the dose-response curve to a point below which there would be no likelihood of cancer incidence. The Subcommittee concludes that the issue cannot be

resolved with our current state of knowledge; hence, we recommend that EPA follow its traditional interpretative procedure of assuming that the two effects are independent of one another. Research to resolve this matter is viewed by the Subcommittee as particularly important and timely, and the Subcommittee encourages EPA to conduct appropriate studies aimed at resolving this matter.

Hyperkeratosis was selected by EPA as the basis on which to select a no-observed-adverse-effect level (NOAEL) based on findings of Valentine (1979), Southwick (1983), and Harrington (1978). The NOAELs derived from those investigations ranged from 3 to 10 ug As per kg body weight per day. Using these NOAELs, EPA applied an uncertainty factor of 5 (rather than the more traditional 10) to derive a drinking water equivalent level (DWEL). While EPA's rationale for the selection and application of an uncertainty factor of 5 is based on a reasonable proposition that the NOAEL was derived from a considerably sensitive group of humans, the Subcommittee favors the use of the larger uncertainty factor of 10, because the size of the cohort (250 individuals) from which the NOAEL was derived is sufficiently small to contribute additional uncertainty.

C. Applicability of Tseng epidemiologic study for estimating cancer risks for the U.S population

Of the many epidemiologic studies that explored associations between ingested arsenic and the increased incidence of cancer, that of Tseng et al. was selected by EPA as pivotal to estimate cancer risks in the U.S. population. That conclusion raises two vital questions: Does the study support a strong positive association between ingested arsenic and skin cancer? And, if ingested arsenic caused cancer in humans, can the Taiwanese data extrapolatable to humans in the U.S. (perhaps due to different eating habits)?

The Tseng study of Taiwanese populations credibly relates, in the view of the Subcommittee, arsenic exposures via tap water to the prevalence of skin cancer and reports a positive dose-response relationship that is usable in estimating cancer risks at much lower doses in tap water.

The extent to which one can confidently extrapolate the Taiwanese findings the U.S. population is governed, in part, by the similarities and differences between the two populations. Among the more salient considerations are the relative differences in water consumption, body mass, nutritional status, and background incidence of skin cancer among members of each country. Additional distinctions taken into some account by EPA are sources of arsenic other than tap water and the presence of organic and physical (i.e., UV light) carcinogens and co-carcinogens (viz., ergot alkaloids) in tap water.

There exists an apparent discrepancy among epidemiologic findings. The studies in Mexico and Germany support the

associations reported by Tseng et al.; however, the few epidemiological investigations carried out in the U.S. failed to find any such association. The Subcommittee concludes that part of the basis for the absence of association in the U.S. studies is insufficient statistical power, given the magnitude of exposure of the US cohorts.

The findings of Tseng et al. (1977), in the opinion of the Subcommittee, are adequate to conclude that ingested arsenic can cause cancer in humans; however, the many differences between the populations of the two countries render inconclusive a confident determination of cancer risk at the levels ingested in the U.S. The Subcommittee concludes that, faced with such uncertainty, EPA is justified in considering arsenic a possible human carcinogen for the U.S. population. However, the many differences between the populations -- particularly nutritional status of those exposed -- should be viewed as overestimating cancer risk from relatively high doses of ingested arsenic; that is, the Taiwanese are to be considered as much more vulnerable to the cancer-causing property of ingested arsenic than are residents of the U.S. On the other hand, the presence of Blackfoot disease in the Taiwan study group could result in an underestimate of cancer risk due to earlier mortality.

The practical outcome of such conclusions, as endorsed by this Subcommittee, is for EPA to consider promulgating a Maximum Contaminant Level Goal of zero based on a cautious policy of public health protection (although as indicated below, some non-zero concentration would likely achieve nearly the same objective). The setting of the MCL should, in our view, be guided by the characterization and utilization of a non-linear dose-response relationship for skin cancer associated with the effective (non-detoxified) dose of inorganic arsenic.

D. Dose-response assessment for ingested arsenic at low doses

There is clear evidence that arsenic ingested at high doses can cause cancer in humans. The risk of skin cancer at doses encountered in U.S. tap water has not been empirically determined. This depends in part on the ability of the human body to efficiently detoxify relatively small doses of ingested arsenic.

Convincing evidence of human metabolism of ingested inorganic arsenic has been presented by the EPA (see Section VIII of the Health Criteria Document). Specifically, conversion by the liver of inorganic arsenic by methylation to monomethylarsenic acid (MMA) and to dimethylarsenic acid (DMA) is the predominant pathway of detoxification in humans. The findings indicate that daily doses of 250 to 1000 ug As^{+3}/person/day or less may be largely detoxified; whereas, at higher doses, the detoxification pathway becomes increasingly saturated, thereby increasing the possibility of macromolecular binding with consequent pathology such as tumor formation. As a result, the slope of the dose-response curve for arsenic-induced

cancer can be expected to be much steeper above intake levels of 250-1000 ug As^{3+}/person/day than at lower levels of intake. The risks of cancer induction at lower levels of intake are then likely to be greatly exaggerated if the relevant pharmacokinetic considerations are not appropriately taken into account. Whether the concentration of As^{3+} reaching target cells is sufficient to pose a significant risk of carcinogenic effects at levels of intake below 250-1000 ug As^{3+}/person/day is problematic. However, because the detoxification at lower doses does not appear to be more than 80 - 90% complete, the possibility of some risk at lower doses cannot be ignored. The Subcommittee concludes that the metabolic evidence for at least partial detoxification is sufficiently persuasive to incorporate it directly into the derivation of an MCL, with appropriate consideration of the known heterogenicity of detoxification in the human population.

E. Arsenic exposure from drinking water and from food

The major source by far of arsenic exposure to the U.S. population is food -- principally beef, chicken, milk products, and fin- and shellfish. Compared to that large background of exposure, the quantity of arsenic contributed from tap water to daily dose is quite low. Moreover, the ability to eliminate or substantially reduce small quantities (i.e., low ppb) is difficult and costly.

The dietary habits of some individuals may result in doses of arsenic that are much higher than the average dose from food products, and both food and water exposures should be considered in assessing arsenic health risks.

F. Apportionment of reference dose across routes of exposure

Currently, EPA sets MCLs for non-carcinogens and for substances classified by EPA as either C, D, or E in a manner that takes explicit account of tolerable levels of exposure from other sources such as food and air. To the extent that reliable data characterizing contributions from other sources are available, EPA incorporates them in the derivation of MCLs. In the absence of such information, EPA arbitrarily assigns 20 percent of the RfD to tap water (10 percent for inorganic substances).

The Subcommittee concludes that EPA's approach appears to be a reasonable management tool -- even for substances classified as C -- because it appears to foster the protection of public health. The Subcommittee cautions, however, that the application of such assumptions may lead in some cases to regulations that are not in the best interest of the public by virtue of being either too restrictive or inadequately protective. Consequently, the Subcommittee, while acknowledging the practical necessity of using default assumptions (e.g., 20% of RfD), strongly encourages the Agency to obtain data that accurately portray human intake from major sources and routes.

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